REMARKS

In the Office Action dated August 28, 2008, the Examiner states that this application contains sixteen groups (I-XVI) of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect to prosecute the subject matter of Group VII, claims 1-19, 23-26, 30-48, 52-55 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is downregulation of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *follistatin*.

Further, in connection with species elections, Applicants provisionally elect acute inflammatory response, and targeting activin A. Applicants submit that within the elected Group VII, claims 1-19, 23-26, 30-48, 52-55 and 59 encompass (and read on) the elected species of inflammatory response; claims 1-14 and 17-19, 23-26, 30-48, 52-55 and 59 encompass (and read on) the elected species of an acute condition; and claims 1-19, 23-26, 30-48, 52-55 and 59 encompass (and read on) the elected species of targeting activin A.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention

only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner alleges that the invention of Group XVI was found to have no special technical feature that defines a contribution over the prior art of U.S. Patent No. 5,545,616. The '616 patent allegedly teaches the use of human follistatin or a humanized antibody to activin in a method of avoiding premature labor. The follistatin and anti-activin antibody must be in a pharmaceutical acceptable carrier for the *in vivo* use. Solely on this basis, the Examiner concludes that the present claims do not present or share a special technical feature that defines a contribution over the prior art.

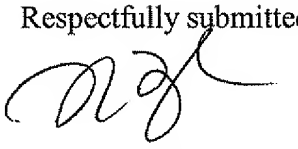
Applicants respectfully submit that the claims of the present application are directed to modulating *inflammation* based on downregulating activin activity. There is no disclosure in the '616 patent of a link between activin and inflammation. Still further, even the broadest method claims of the present application are directed to methods of modulating *inflammation*. The disclosure of the '616 patent, relating to a method of avoiding premature labour, is irrelevant to the present invention.

At the very least, Groups VII-XV should be examined together, as these groups are all directed to *methods* based on *downregulating activin activity*. This special technical feature, shared by Groups VII-XV, is nowhere taught or disclosed in the '616 patent. Therefore, it is submitted that at least the claims of Groups VII-XV, when considered as a whole, defines a contribution over the prior art, and should be examined in the same application.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined sixteen groups, one from another, as presented by the Examiner.

Accordingly, it is respectfully submitted that the present claims satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, or at least the claims of Groups VII-XV.

Respectfully submitted,



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